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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/086,138	05/28/1998	ROBERT L JAFFE	ETLIP002US	7877

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EXAMINER

GITOMER, RALPH J

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 04/28/2003

131

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/086,138

Applicant(s)

Jaffe

Examiner

Ralph Gitomer

Art Unit

1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 7, 2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

The amendment received 1/7/2003 has been entered and claims 1-15 are currently pending in this application. The priority date of the present specification is granted to 5/28/1998.

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Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

10

The addition of a measure of the toxicity of any combination of potentially cytotoxic substances can be obtained to claim 1 is new matter. This feature is not disclosed in the specification as originally filed.

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

25

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Jaffe.

Jaffe (5,387,508) by the present inventor entitled
"Detection of Cytotoxic Agents Using Tetramitus Rostratus"
teaches in claim 3 first paragraph, the sample may be a liquid,
gaseous or solid material. Various types of whole effluent
5 samples are taught.

It is noted the present specification on page 2 last
paragraph discusses '508 where '508 does not disclose a WET test
in which all of the potentially toxic substances from the sample
are evaluated in a natural combination. See in '508 Example 5 in
10 column 6 where a WET sample is tested. See the claims.

All the features of the claims are taught by Jaffe for the
same function as claimed.

15 The following is a quotation of 35 U.S.C. 103(a) which forms
the basis for all obviousness rejections set forth in this Office
action:

20 (a) A patent may not be obtained though the invention is not identically
disclosed or described as set forth in section 102 of this title, if the
differences between the subject matter sought to be patented and the prior
art are such that the subject matter as a whole would have been obvious at
the time the invention was made to a person having ordinary skill in the
25 art to which said subject matter pertains. Patentability shall not be
negated by the manner in which the invention was made.

Claims 3-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jaffe.

Jaffe (5,387,508) by the present inventor entitled "Detection of Cytotoxic Agents Using Tetramitus Rostratus" teaches in claim 3 first paragraph, the sample may be a liquid, gaseous or solid material. Various types of whole effluent samples are taught.

It is noted the present specification on page 2 last paragraph discusses '508 where '508 does not disclose a WET test in which all of the potentially toxic substances from the sample are evaluated in a natural combination. See in '508 Example 5 in column 6 where a WET sample is tested. See the claims.

The claims differ from Jaffe in that additional flagellates are claimed, dilutions of sample are specified, filtering is described.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ flagellates other than T. Rostratus because in view of the teachings of Jaffe, one would have a high expectation of success in employing any known flagellate with the requisite qualities taught in the present specification. It is noted that the present specification teaches specific methods and examples only for T rostratus.

Further, the present claims recite the sample is combined with the culture directly.

In `508 column 3 first paragraph, ~~the~~ samples may be concentrated, or, in the case of solids, suspended in a liquid, prior to testing.~~the~~ It would appear the sensitivity of the test would be dependent upon the concentration of the cytotoxic substances and to dilute or concentrate samples to make them more suitable for a given test is well known in this art and taught by `508, see column 7 Table 2.

Applicant's arguments filed 1/31/00 have been fully considered but they are not persuasive.

Applicant argues that the present claims require the whole effluent sample is combined directly with the culture which means there is no requirement for concentration of the sample prior to combining it with the culture. Examples 5 and 6 of Jaffe are not WET tests because a toxic substance is added to the sample. To suggest that Jaffe teaches concentration of the sample is optional does not extrapolate to a WET test. Only hindsight in view of Jaffe would teach a WET test. Jaffe does not teach any flagellates other than *T. rostratus*. The limitations of claims 7 and 11 have not been addressed. A Declaration by the inventor is presented which states the EPA definition of WET test and Examples 5 of Jaffe is not a WET test because it was contrived to evaluate the flagellates adaptation and immunity abilities.

It is the examiner's position that the specification and claims of '508 consider the feature of concentrating the sample optional, see discussion presented above. In example 5 of Jaffe, the sample is fumes from a rubber stamp manufacturer and no concentration of the fumes is recited. Jaffe teaches conclusions of the results of Example 5 as ~~an~~ An inexpensive identification procedure would then be possible prior to costly qualitative/quantitative analyses.~~is~~ This would appear to mean the test was contrived to be an effective analysis.

It is noted in present claim 1(a) the step is ~~obtaining~~ a sample for testing suspected of containing a plurality of potentially cytotoxic substances~~is~~ is not limited to any particular type of sample. For example, the sample could be a concentrated sample which would accomplish the function stated in the preamble. No other limitations are presented regarding the type of sample or its concentration in the claims. Therefore, the present claims read on a concentrated sample as taught by Jaffe. The present specification teaches in page 9 for example, various dilutions of sample are required to obtain the desired information which includes both dilution and concentration.

Applicants are reminded that the invention is the subject matter defined by the claims, and the limitations of the specification are not read into the claims where no express statement of that limitation is included in the claims, see In re Priest, 199 USPQ 11.

The Applicants remarks with regard to the Examiner's use of improper hindsight have been noted but the reference clearly shows the claims rendered obvious for reasons discussed above. The fact that the Applicants have selected specific teachings from this reference is still deemed obvious. At the time this invention was made the teachings of the reference was clearly in the public domain and one of ordinary skill in this art knowing of this reference could have selected as the Applicants have done.

Regarding the selection of a specific flagellate, the present specification appears to enabling for *T. rostratus*. See the present specification on page 4 second paragraph which is confusing regarding the question mark in line 12 and suggesting *Tetramitus* is unsuitable for marine water samples but none are taught. No advantage of any other flagellate is specifically taught and an undisclosed advantage is given little or no weight. All the functions of the present claims are taught by the present specification for only *T. rostratus*.

Regarding the limitations of claim 7 directed to filtering (which reads on concentrating), and claim 11 directed to particulates, Jaffe teaches concentrating particulates in column 7 Example 8, and filtering is a known method of concentrating particulates. It would appear applicants are masking the invention at hand by focusing on obvious and irrelevant subject matter.

Regarding claim 4 directed to dilution of the sample, dose response curves are well known in this art and the step of diluting for such a function is not novel.

5 Claims 1-15 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

10 In claim 1, ~~such~~ that a measure of the toxicity of any combination of potentially cytotoxic substances can be obtained~~is~~ is indefinite regarding how the substances are potentially toxic to what is not seen and ~~can be obtained~~ does not specify how it is obtained nor from what.

15 Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (703) 308-0732. The examiner can normally be reached on Tuesday-Friday from 8:00 am - 5:00 pm.
20 The examiner can also be reached on alternate Mondays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (703) 308-4743. The fax phone number for this Art Unit is (703) 308-4556. Any inquiry of a general nature or relating to the status
25 of this application should be directed to the Group receptionist

Serial No. 09/086,138
Art Unit 1651

-9-

whose telephone number is (703) 308-1235. For 24 hour access to
patent application information 7 days per week, or for filing
applications electronically, please visit our website at
www.uspto.gov and click on the button Patent Electronic Business
Center for more information.



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